DEC 1 9 2001

K013616
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Appendix V - 510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

Classification Name: Intramedullary Fixation Rod
Common Name: Humeral Rod
Proprietary Name: Polarus Cap Screw
Proposed Regulatory Class: II
Device Product Code: HSB
Manufacturing Facility: Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, OR 97005 U.S.A.
Establishment Registration No.: 3025141
Contact: Shari Jeffers
Labeling/Promotional Materials: See Appendix III
Substantial Equivalence: This product is similar in design to the set screw for the Howmedica Vitallium IM Device, the Ace Medical AIM Titanium Humeral Nail System's end cap, the Alta IM Rod's cap screw, and the SynthesTitanium Solid Humeral Nail System's end cap. Literature on these predicate devices is included in Appendix IV.

The Polarus Cap Screw is intended to be used in conjunction with the Polarus Rod family cleared under K920666 and K951740. Its purpose is to engage the proximal-most 5.0 interlocking screw in the rod to prohibit/minimize backing out of that screw and to prohibit ingrowth of bone into the 1/4-20 hole. The Polarus Cap Screw is manufactured from two different materials. The cap is manufactured from a titanium alloy per ASTM F 136 and the tip portion is manufactured from medical grade polyethylene per ASTM F 648.

The Polarus Cap Screw is provided sterile and is packaged in inner and outer PETG blisters with Tyvek lids. Sterility is achieved by a minimum of 2.5 megarads gamma radiation. Verification of sterility is performed using the AAMI - Method 1. Sterility assurance level is 10^{-6}. We make no claims as to the pyrogenicity of this product. Instrumentation is provided nonsterile in a tray. On file at Acumed is data which shows that the instrumentation can be successfully steam sterilized under specific process parameters which will obtain a resulting SAL of 10^{-6}.

Predicate devices that are substantially equivalent to Acumed's Polarus Cap Screw are the set screw for the Howmedica Vitallium IM Device, the Ace Medical AIM Titanium Humeral Nail System's end cap, the Alta IM Rod's cap screw, and the SynthesTitanium Solid Humeral Nail System's end cap. These devices are similar in indication, intended use, material (titanium) design, and size to Acumed's Polarus Cap Screw.

Based on the similarities between the Acumed Polarus Cap Screw and its predicate devices, the safety and effectiveness of the Acumed Polarus Cap Screw is expected to be similar to the predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 18, 2013

Acumed Incorporated
% Ms. Shari Jeffers
Regulatory Affairs
10950 SW 5th Street, Suite 170
Beaverton, Oregon 97005

Re: K013616
Trade/Device Name: Polarus Cap Screw
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 4, 2001
Received: November 5, 2001

Dear Ms. Jeffers:

This letter corrects our substantially equivalent letter of December 19, 2001.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013616

Device Name: Polarus Cap Screw

Indications For Use:

The Polarus Cap Screw is intended to be used in conjunction with the Polarus Humeral Rod. It engages the 5.0 mm proximal screw in the rod to prohibit / minimize the screw from backing out and to prohibit the in growth of bone into the 1/4 - 20 hole.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013616

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)